Justification for Other than Full and Open Competition.

1. Contracting Activity:

Department of Veterans Affairs (VA)
Office of Acquisition Operations
Strategic Acquisition Center- Frederick
321 Ballenger Center Drive, Unit 125
Frederick, MD 20703

2. Description of Action:

The proposed sole source action is for a new four (4) year firm-fixed price (FFP) Indefitite Delivery Indefinite Quantity (IDIQ) contract for maintenance and service, and hardware replacement for Topcon Non-Mydratric Cameras in twenty-one (21) VISNs at over 300 sites. The intent is to award the IDIQ contract non-competitively to Topcon Medical Systems, 37 W. Century Rd., Paramus, NJ 07652 and then place orders annually based on VHA's needs.

3. Description of Supplies or Services:

In Fiscal Year 2000, Congress directed VA to implement deferential imaging to screen for diabetic retinopathy. VA purchased over 700 Non-Mydriatic cameras from Topcon Medical Systems between 2005 and 2013. A three year contract for upgrades and service for those systems purchased 2005 through 2008 expires on September 20, 2013. Following the expiration of this contract, those systems greater than three years old will require service and potentially upgrades.

The VHA Office of Telehealth Services has identified this need and requested the contractor's services to meet this need. The proposed action is to provide continued maintenance and service on the more than 700 Non-Mydriatic Camera Systems in use throughout the VA. The contractor will provide all management, supervision, labor, materials, and supplies needed to provide the required maintenance and services. Maintenance and services will include ongoing maintenance of existing systems and on-site replacement of hardware. Contractor will extend the warranty (covering all parts and labor) on all components - including TRC-NW8S - for 3 full years as well as provide unlimited phone/VPN support to troubleshoot all system issues.

The total estimated value of the proposed Indefinite Delivery Indefinite Quantity (IDIQ) Contract is \$4,115,275.00,

4. Statutory Authority:

The statutory authority permitting other than full and open competition is 41 U.S.C.3304(a)(1) as implemented by the Federal Acquisition Regulation (FAR) Subpart 6.302-1 entitled, "Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements."

5. Rationale Supporting Use of Authority Cited Above:

As stated in Section 3 above, through a national contract, VA has purchased over 700 Non-Mydriatic cameras from Topcon Medical Systems, including the TRC-NW6S Non-Mydriatic Retinal Fundus Camera System purchased between FY05 and FY08, and the TRC-NW8 Non-Mydriatic Retinal Fundus Camera System purchased FY08 through FY13.

The hardware and software for the above purchased teleretinal camera systems is proprietary to TopCon Medical Systems and no other vendor aside from TopCon Medical Systems can or will provide maintenance, service, and warranty to the equipment. Aside from the proprietary nature, TopCon is the manufacturer of the equipment and is uniquely positioned to provide the expertise needed to provide continued maintenance and service of the large number of systems in service across 21 VISNs.

6. Efforts to Obtain Competition:

Market research was conducted, details of which are in the market research section of this document. This effort did not yield any additional sources that can meet the Government's requirements. There is no competition anticipated for this acquisition. Additionally, the proposed action will be synopsized on the Federal Business Opportunities page in accordance with FAR 5.201. If as a result of this synopsis, capable interested vendors express an interest in proposing to this requirement, they will be provided a copy of the solicitation and be permitted to compete for this requirement.

7. Actions to Increase Competition:

The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed.

8. Market Research:

- a. IAW FAR Part 10, market research was conducted to determine suitable approaches to acquiring the required TopCon Imaging Systems Maintenance and Service. Prior to researching, the belief was that only TopCon could provide the needed maintenance and repairs, as well as extend the warranty as required by VHA. This notion is supported by the TopCon Medical Systems Terms of Sale for IMAGEnet language which indicated "warranty does not cover damage due to...servicing not authorized by TopCon ...failure to perform required maintenance, and/or problems caused by use of parts and components not supplied by TopCon." Additionally, According to the PMO, market research performed before the prior award for the same services indicated the need to sole-source award to TopCon Medical Systems.
- b. Market research was conducted to determine 1) Whether any other businesses could meet VHA's requirement for Retinal Imaging Systems Maintenance and Service, and 2) Of these with capability, whether any small businesses could fulfill the need.

Lopcon Retinal imaging Systems Maintenance

- (1) A search of VA FSS schedules (65 II A and 66) was conducted for companies capable of providing TopCon equipment/ parts. The following companies (aside from TopCon) were noted as providing TopCon equipment: Lombart Brothers, Opthalmic Instruments, Inc., Optics, Inc., The Walman Optical Company, Universal Opthalmic Instruments, and Holman's Inc. A review of each schedule revealed that although parts and hardware were offered, none offered the needed maintenance and service.
- (2) An internet search/ search for companies that could potentially provide maintenance on TopCon equipment revealed that Canon U.S.A (large business), National Instrument Service Corp (NISCorp)(unknown size), Lombard Instruments (unknown size), and TopCon Medical Systems (large business) either provide or service TopCon or similar equipment.

- (3) Additional Market Research was conducted using the SBA Dynamic Small Business Search engine, using the keywords "TopCon(13 results)"; "Retinal(3 results)"; "Retinal Camera(0 Results)" "Medical Repair (3 results), and "Retinal Imaging (0 results)." A review of the profiles and websites of companies found using the above keywords resulted in only two companies with potential capability to perform:
 - Ophthalmic Instruments & Consulting; and
 - Universal Ophthalmic Instruments (UO!).

A copy of the statement of work was provided to both companies on June 30, 2013, with a request for capability and interest in meeting the requirement. Neither company provided a response by the date and time given in the email request. Subsequent phone calls to each company revealed the following:

Ophthalmic Instruments & Consulting reviewed the Statement of Work and determined that it could not meet the requirement. The POC indicated that with regards to the IMAGEnet software, any upgrades (half of the work requested) would require the installation of proprietary TopCon R4 Software

since the IMAGEnet 2000 software is no longer available to outside vendors.

The responses provided from each of the companies contacted through market research (from both the internet search and through the SBA Dynamic Small Business Search) indicate that only TopCon is uniquely positioned to provide the necessary maintenance, services, upgrades, and warranty extension as required by VHA. To meet the requirement, VA will negotiate a non-competitive award to TopCon Medical Systems for Maintenance and Repair of the 700+ Retinal Imaging Systems originally purchased off the Mandatory VA FSS National Schedule.

9. Other Facts:

Full and open competition is precluded by the fact that VA has purchased and owns more than 700 Non-Mydriatic cameras that were manufactured by and that have software proprietary to TopCon Medical Systems. Telehealth Services have established a robust Teleretinal Imaging Program throughout the VA and active in all 21 VISNs. By competing the purchase of these systems on the mandatory National VA Contract and awarding to TopCon Medical Systems, these retinal imaging systems were essentially made the de-facto standard in VA. The medical and practical benefits of continuing this service and maintenance contract is important for continued standardization and reliability, from both a business and medical standpoint.

10. Fair and Reasonable Cost Determination:

The anticipated price to the Government for this contract action will be determined to be fair and reasonable based on previous purchases for similar/same services and published commercial pricing.